

REMARKS

By this Amendment, Claim 8 has been amended to place this application in immediate condition for allowance.

In the outstanding Office Action, the Examiner has rejected Claims 8-17 under 35 U.S.C. 112, second paragraph, as allegedly being indefinite. In this regard, the Examiner has indicated that in Claim 8, lines 1-2, "it is unclear if the lancet or the lancet device has 'a body'." In order to overcome this ground of rejection, amendments have been made to the preamble of Claim 8 to delete "a needle or blade positioned therein" and to add --of said lancing device-- so that the preamble of Claim 8 now reads as follows:

"A lancet for use with a lancing device having a body and a needle cover, said body and needle cover of said lancing device being formed from plastic, said lancet comprising ...".

Additional amendments have been made to sub-paragraph a) in further clarification. As such, it is respectfully submitted that Claims 8-17 are now fully definite.

In the outstanding Office Action, the Examiner has rejected Claims 8-17 under 35 U.S.C. 103(a) as allegedly being unpatentable over U.S. Patent No. 3,358,689 to Higgins in view of U.S. Patent No. 3,330,004 to Cloyd et al. In taking this position, the Examiner has acknowledged that the ports 16 of Higgins are only "opposed" since they are on opposite sides of the body 11. The Examiner has relied

upon Cloyd et al. for the teaching of a bend 6 or 30 in the needle thereof to prevent inadvertent removal.

Applicants respectfully disagree with this position as taken by the Examiner. Higgins teaches an integral lancet and package, whereas Cloyd et al. teach a hypodermic syringe. Thus, the teachings of the references applied by the Examiner arise from diverse non-analogous arts. As such, it is respectfully submitted that one of ordinary skill in the art of lancets would not consider the teachings of Cloyd et al. to be pertinent to the problems associated with the present invention.

Moreover, in the present invention, the ports in the plastic body are not only diametrically opposed, but are aligned with one another. This is not the case concerning the ports 16 of Higgins. In Higgins, the ports 16 are disclosed as "narrow transversely extending slots 16." Column 2, lines 37-8, Higgins. As shown in Figure 13, when the Higgins device is manufactured, plates 75, 76 and 85 engage the lancet 20 during the molding process. This structure precludes the lancet 20 from pivoting in the mold 70, 80. If the plates, for example, 75 and 85, were diametrically opposed and aligned, the lancet 20 could pivot within the mold.

In the present invention, the ports are formed by diametrically opposed jaws 41 and 42 inserted within the mold when the inventive device is being manufactured, and having sufficient width to preclude the above-described pivoting.

Accordingly, Claim 8, the sole independent claim at issue, has been amended to specify that the opposed ports in the plastic body are both "diametrically" opposed and "aligned." This structure is nowhere taught or suggested in Higgins or, for that matter, in Cloyd et al., who also teach the misaligned ports in their mold (Figures 3 and 4) used to bend the needle 3 thereof. As such, by the amendments described above, the present invention is believed to patentably distinguish from the combination of Higgins and Cloyd et al. under the provisions of 35 U.S.C. 103(a). Taking the disclosure of Higgins and Cloyd et al. as a whole at the time the present invention was made, it could not possibly have been obvious to one of ordinary skill in the art to provide diametrically opposed aligned ports in the plastic body thereof. Based upon Claim 8 as amended, the only place the Examiner could go for the suggestion to modify the cited prior art to render the ports diametrically opposed and aligned, would be in Applicant's own disclosure. Of course, the hindsight reconstruction of the prior art in light of Applicant's own disclosure is a practice forbidden in Patent Law.

Accordingly, it is respectfully submitted that Claims 8-17 are patentable over Higgins and Cloyd et al.

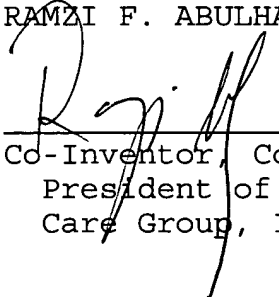
In the outstanding Office Action, the Examiner has rejected Claims 8-17 under the judicially created doctrine of obviousness-type double patenting. In response, accompanying this Amendment are separate Terminal Disclaimers for the two patents relied upon by the

Examiner, U.S. Patent Nos. 6,589,261 and 6,723,111. Each Terminal Disclaimer is submitted along with the appropriate Terminal Disclaimer Fee of \$65.00.

Accordingly, for the above reasons, reconsideration and allowance of this application are respectfully solicited.

Respectfully submitted,

RAMZI F. ABULHAJ



Co-Inventor, Co-Applicant and
President of Assignee Vital
Care Group, Inc.

Ramzi F. Abulhaj
VITAL CARE GROUP, INC.
8935 Northwest 27th Street
Miami, FL 33172
(305) 620-4007